

## **REMARKS**

### Objections to Specification

The specification has been amended to address the informalities identified by the Examiner. The document incorporated by reference has been amended to identify the document more precisely. The text of the specification has been amended to mention the identified reference numerals of the drawings.

### 102 Rejections

The Office Action cites O'Mahoney, et al (6,585,675) as anticipating claim 1. Specifically, the Office Action argues that claim 1 is anticipated by O'Mahoney's description of combining pressure drop detection with air detection to prevent the pressure drop being interpreted as a withdrawal line disconnection. Claim 1 is amended such that it requires "detecting a leak of blood from an extracorporeal blood circuit." As such, Applicants propose that with this limitation, the detection of pressure loss and air intrusion as shown by O'Mahoney, et al does not show "two independent ways to generate at least two leak detection signals" as required by the claim. That is, neither of the two mechanisms detects leaks of blood from a circuit. Rather the two mechanisms combined in the logical equation cited are for detecting the leak of fluid (air, in practice) into the withdrawal line. O'Mahoney, et al say the function "is a reliable detection of a withdrawal line disconnection, while avoiding false alarms." As also stated in O'Mahoney, et al, the disconnection of a withdrawal line causes air to infiltrate. For the foregoing reasons, Applicants propose the rejection of claim 1 with regard to O'Mahoney, et al is overcome.

Claims 2 through 6 also distinguish O'Mahoney, et al, as a result of the amendment of claim 1 and also because of the additional recitation they contain, as discussed below.

Claim 2 stands rejected as anticipated by O'Mahoney, et al. New claim 49 is based on original claim 2, but, has been redrafted to place it in independent form. Claim 49 includes "said deriving includes calculating a probability of a leak responsively to said at least two detection signals." The Office Action states that this limitation is inherent in O'Mahoney, et al, based on the premise that O'Mahoney, et al show a logic function that the controller executes in which a disconnection is not indicated by the system unless two simultaneous conditions are met. "In

relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” MPEP §2112.IV. The conditions presented by O’Mahoney are a change in pressure in the withdrawal line and the presence of air. This does not correspond to the calculation of a probability. In O’Mahoney, et al, the detected conditions produce a certain output that is either yes or no, there is no probability generated. Therefore the claimed features do not “necessarily flow[] from the teachings” of O’Mahoney, et al including the logic function of the controller of O’Mahoney.

Claim 5 stands rejected as anticipated by O’Mahoney, et al. New claim 50 is based on original claim 5, but, redrafted to be in independent form. Claim 50 includes “said deriving includes applying a respective weight to said at least two leak detection signals and adding them.” The Office Action states that this limitation is inherent in O’Mahoney, et al, based on the premise that O’Mahoney, et al show a logic function that the controller executes in which a disconnection is not found unless two conditions are met. O’Mahoney, et al do not show applying respective weights or adding signals as required by the claim. The Office Action does not provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art, but simply quotes the claim and points to the simple logic function as anticipating it. The claimed features are not inherent in the logic function of the controller of O’Mahoney, et al because they do not flow from its teachings.

Claim 6 stands rejected as anticipated by O’Mahoney, et al. New claim 50 is based on original claim 5, but, redrafted to be in independent form. Claim 50 includes “said detecting includes sensing a presence of fluid outside said blood circuit and detecting a presence of air inside said blood circuit.”

detecting a leak... to generate at least two leak detection signals; deriving at least one composite signal responsive to said two leak detection signals; generating an alarm signal responsively to said at least one composite signal, wherein said detecting includes sensing a presence of fluid outside said blood circuit and detecting a presence of air inside said blood circuit.

The Office Action states that this limitation is inherent in O'Mahoney, et al, based on the premise that O'Mahoney, et al show the detection of various parameters such as motor currents, air in blood, motor speed, pressure in the blood circuit. However, O'Mahoney, et al do not show detecting a leak including detecting includes sensing a presence of fluid outside the blood circuit and detecting air inside the blood circuit and deriving a composite signal responsive to the two leak detection signals. The Office Action does not provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art, but simply quotes the claim and points to the simple logic function as anticipating it. The claimed features are not inherent in the logic function of the controller of O'Mahoney, et al because they do not flow from its teachings.

Claim 9 stands rejected as anticipated by O'Mahoney, et al. Claim 9 has been amended to over come the rejection. Applicants propose that O'Mahoney, et al do not show the defined structure. In particular, Applicants note that the disclosure relied upon in the Office Action relates to effects caused by air flowing into a blood line and therefore claim 9 clearly distinguishes O'Mahoney, et al. For the same reasons, the claims depending from claim 9 are distinguished as well.

Claims 10 through 12 also distinguish O'Mahoney, et al, as a result of the amendment of claim 9 and also because of the additional recitation they contain, as discussed below.

Claims 13 and 19 are amended by incorporating the limitations of their base claims such that their scopes match those of the rejected base claims. The claims were rejected as anticipated by O'Mahoney et al. However, there is no indication in the Office Action of the bases for these rejections. The Office Action provides some bases for the rejections of claims 1-6, but rejects all the remaining claims on the same grounds. Yet claims such as claims 14 and 19 contain very different limitations from those in claims 1-6 so it is not clear what the grounds of the rejection were. O'Mahoney et al has been reviewed and Applicants were unable to find an anticipation of the limitations of these rejected claims. Withdrawal of the rejection is therefore requested.

Claim 25 has been amended. Claim 25 includes at least the limitations identified with respect to claims 13 and 19, and therefore, the basis for the rejection of claim 25 was not found in the Office Action. Claim 25 was amended to clarify by indicating that at least two different detector signals are combined. Claims 26, 27, 32 and 33 depend from claim 25. Since they

incorporate the limitations of the base claim, for the foregoing reasons, the Office Action also lacks a basis for their continued rejection.

Claim 42 was rejected as anticipated by O'Mahoney et al. However, there is no indication in the Office Action of the basis for the rejection. The Office Action provides some bases for the rejections of claims 1-6, but rejects all the remaining claims on the same grounds. Yet claim 42 contains very different limitations from those in claims 1-6 so it is not clear what the grounds of the rejection are. O'Mahoney et al has been reviewed and Applicants were unable to find an anticipation of the limitations of these rejected claims. Withdrawal of the rejection is therefore requested. Claims 43-48 depend from claim 42. Since they incorporate the limitations of the base claim, for the foregoing reasons, the Office Action also lacks a basis for their continued rejection.

New claims 49-61 are added.

**CONCLUSION**


In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration of this Application and the prompt allowance of at least claims 1-6, 9-13, 19-20, 25-27, 32-33, and 42-61.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-3840. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).**

Respectfully submitted,

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